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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,966	09/05/2001	Peter Lea	874-35/AMK	3575

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EXAMINER

SIEPKE, SAMUEL P

ART UNIT PAPER NUMBER

1743

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/831,966

Applicant(s)

LEA, PETER

Examiner

Samuel P Siefke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims **40-52** and **59-60** are rejected under 35 U.S.C. 102(b) as being anticipated by Nason (USPN 4,790,640).

Nason discloses an improved laboratory slide for the analysis and testing of liquid specimens. A specimen application site at one exposed end of the slid receives a specimen thereon which is drawn via capillary action along the flow channel into contact with reagent-coated beads. At the specimen application site is disposed a porous filter element 134 that is secured onto the slide plate (fig. 7). The filter element is conveniently included to filter a liquid specimen applied to the well 130 to removed selected particles or cells therefrom prior to specimen flow along the flow channel 129. The filter element can be used to filter and trap red blood cells from a blood specimen thereby separating the serum for flow through the flow channel (col. 7, lines 3-15). The beads may be coated with a reagent, such as an antibody (col. 1, lines 15-20). When the specimen containing an antigen of interest is introduced into the slide and flows through the channel to contact the beads, the antigen is deposited onto the beads by binding to the antibody on the beads. The beads are disposed in abutting relation, and

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the sample flows through the spaces between the beads by capillary action (col. 9, lines 35-44). A colorimetric change indicates of a positive or a negative reading for a given test procedure. (col. 8, lines 1-5). The reagent is printed onto the interior of the capillary channel (col. 7, lines 12-15). A determined volume of a fluid sample is applied to the capillary channel (col. 2, lines 47-54). Nason discloses that a plurality of capillary channels may be employed in order to analyze multiple samples (col. 7, lines 40-45; fig. 8). An elongated stretch of the flow channel follows the second reagent and may be associated with a variety of indicia, such as time markings, color indications, and the like for use in interpreting test stream from a final enlarged chamber within which the final test reading may be taken (col. 8, lines 25-34). With this arrangement, multiple reagents and multiple holding times can be built into a single laboratory slide. The laboratory slide is useful in performing a wide variety of clinical tests, a dip test (col. 9, lines 3-20).

Nason does not teach recording results of the assay in a computer database and further applying algorithms to the data to generate profiles of one or more selected disorders and statistical information.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **53-58** are rejected under 35 U.S.C. 103(a) as being unpatentable over Nason (USPN 4,790,640) in view of Fisher et al. (USPN 5,656,046).

Nason discloses an improved laboratory slide for the analysis and testing of liquid specimens as discussed above.

Nason does not teach analyzing data and applying statistical or algorithms to the data collected.

Fischer teaches a fully automated spectrophotometric analyzer and method used for testing blood samples in the clinical laboratory for thrombosis and homeostasis properties. The method includes detecting a reaction in the well and measuring the data from the reaction, processing means for mathematically processing the measured data to evaluate a change in or magnitude of the measured data from the reaction in the well, and reporting means to report said results of the evaluation by the processing means (col. 3, lines 51-67; col. 20, lines 20-60). A bar code is used for identifying means while transporting the sample and reagent through the stations (col. 11, lines 48-60). It would have been obvious to one having an ordinary skill in the art to modify

Nason to include the sample analysis means of Fischer in order to provide a stand alone laboratory method that has sample preparation, optical inspection, data analysis and total quality control for precise analysis.

Applicant's arguments filed 10/27/04 have been fully considered but they are not persuasive. Applicant argues, "Nason does not disclose or suggest a methodology involving the used of a dynamic filter in an assay device that would separate a liquid from non-liquid components of a sample." The Office would like to point out to co. 7, lines 3-15 where Nason discloses a filter that filters out a non-fluid component.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sam P. Siefke



January 7, 2005


Jill Warden
Supervisory Patent Examiner
Technology Center 1700